Colony Management and Beyond

Over the last five to seven years the Biopharma Industry has spawned many new branches of science. In recent times we have seen the emergence and acceleration of the Genomic Sciences. At the center of Genomic Science is the ability to manipulate DNA by either inserting or deleting particular genes of interest. Scientist today have the ability to genetically manipulate the genome of most animal species with the purpose of studying how these genes influence or play a role in the causes of human diseases.

This relatively new field of science has come to manifest itself within the incarnation of Genetically Modified Animal Models (Transgenic Animals). Most Universities, Biotech's and Pharmaceutical companies have already created, or are in the process of developing large populations of transgenic animals. Many of these companies already have thousands of transgenic animals confined within their laboratories. The vast majority of these transgenic animal models, about 90%, consist of rodent species such as mice and rats, with the remaining 10% of the industries transgenic animal population consisting of other animal species such as goats, chickens, pigs, cattle, etc.

As a result of this large and dynamic population of transgenic animals, many companies are struggling and searching for better ways to effectively apply computer technologies to manage the data related to the development of their transgenic animal models. Most companies currently have some limited form of computer software that is being used to manage transgenic animal data. One astonishing and embarrassing fact that exists is that most research facilities are still only using very rudimentary spreadsheets to manage this mission critical research data. The use of these deficient spreadsheet tools has resulted in the average research facility only being capable of tracking a very minimal amount of data with a very low level of data integrity. This has had some serious consequences on their ability to perform advanced data analysis and is the primary cause of some serious bottlenecks in the progress of their research.

Over the last few years some midsized companies have started to outgrown their spreadsheets and have started to deploy software packages known as colony management software. These simple colony management solutions solved some of the basic problems that researchers were facing when they were only using rudimentary spreadsheets, but they do not address the larger problems of Project

Management, Workflow Control, Animal Management, and cross department data flows. Unfortunately, most of the companies who have gone this route will soon come to realize that these colony management solutions are only a temporary short-term fix to a much larger and much more complicated operational problem.

The strategic error that these midsize companies are making is that they have significantly underappreciated the importance of the problem, and in so doing, the scope of the problem has been defined much too narrowly. This will result in much larger problems down the road as the amount of data increases and the speed at which data needs to be utilized increases. Companies will not be able to meet their minimum research demands as a result of the existing limitations in colony management software. In most cases this will not be recognized until the software that they have been using has reached a point of catastrophic failure.

Many of these companies will very quickly outgrow the basic capabilities of their colony management software and once they realize that they still have not achieved any project control will again be searching for a more comprehensive solution to meet their needs. Colony Management Software does not solve nor does it achieve any project control. For those companies seeking to advance their research it will be very important for them to quickly recognize this, and then to acknowledge these existing limitations of their colony management software. The sooner they make this admission, the sooner they will be able to move forward and remedy the real problem of project management.

In order to achieve a successful transition and outcome it will be necessary for companies to commit to a new strategic plan and purchase a much more sophisticated database system known as a Transgenic LIMS. The term LIMS is an acronym for Laboratory Information Management System. A Transgenic LIMS is specifically designed for use in the development of Genetically Modified Animal Models. A Transgenic LIMS is ultimately what all companies will eventually have to have in place in order to help them maintain project control as well as to manage the vast amount of genomic data that continues to accumulate as their transgenic animal populations continue to increase in size.

Other companies have made the short-sided mistake or are in the process of making similar errors in judgment by thinking that colony management is the crux of their data management and research bottleneck problems. For many companies struggling with this issue and who are now trying to solve this problem, colony management software will only provide a short-term quick fix to a complex long-term strategic need. Many companies will make the costly mistake of defining their long-term needs as simply just that of being able to track existing animal populations and cage management. Many investigators might also buy into this idea and agree with this view because they have reached a point of desperation and they are now willing to settle for any automation improvements that they can get.

In the short term colony management software will help to provide the minimal amount of organization control that investigators need to continue their research. Unfortunately as the scientific demands of their research increases, it will very quickly become apparent that it is not the final answer. The greatest limitation that colony management software has is that it is limited to performing only colony management. Unfortunately the operations of a Core Research Facility reach far beyond that of just managing the data of a lone investigators colony of transgenic mice. In fact, colony management data only represents about 15% of the total amount of data that needs to be tracked and managed. That is not to say that colony management is not an essential component of the research data, but it is only the tail end piece of a much more complex flow of data that originates much further upstream in the scientific process.

Many larger companies have already come to recognize that colony management software alone is not capable of providing the advance infrastructure that is needed to perform and support high throughput genomic research. In fact, none of the existing colony management software that is available on the market is capable of providing the basic foundation to start this process. This reality has only come to the forefront as some of the larger companies have reached a point in the evolution of their research to recognize the limits of these outdated colony management applications. As a result these larger companies are now scrambling to locate or build a more industrial strength technology in the form of a Transgenic Laboratory Information Management System (Transgenic LIMS).

What is a Transgenic Laboratory Information Management System?

A Transgenic LIMS is a much more sophisticated powerful database management system that is designed and architected specifically for the use in Transgenic Animal Research. It goes far beyond the limitations of

simple colony management software. First, a Transgenic Laboratory Information Management System will span the operational boundaries of multiple departments within a Core Facility. It provides a more global approach to integrating the complex scientific processes and workflows. It is going to allow for better communications between departments as well as complete integration of all data between departments. It is going to eliminate data redundancy and improve the quality and accuracy of data across these same operational boundaries. The differences between a Transgenic LIMS and colony management software, is the equivalent difference between a Volkswagen Bug, and the Space Shuttle.

About 85% of the critical scientific data related to the development of Transgenic Animal Models is generated upstream in the scientific workflow. It is this vast amount of upstream data that represents the bulk of the important genomic related details that scientist are in dire need of performing analysis against. As the transgenic animals progress through the workflow, it is this upstream data that needs to flow downward into the colony management process and then beyond into the preclinical process.

This is where a Transgenic LIMS becomes important. A Transgenic LIMS provides a comprehensive framework in which all of the scientific data is fully integrated from start to finish. This means that as each specific animal model is being developed, all of the developmental data moves through the workflow with the animal. When the animal is then moved into a production breeding process and/or then into a preclinical study, all of the relevant data is already in place and available for study. Investigators will have immediate access to the complete genetic history of the animal as well as all clinical data and everything else that is essential for the study.

Workflow Management

What capabilities should you look for in a Transgenic LIMS. A well-designed industrial grade Laboratory Information Management Systems should follow a workflow methodology. This means that you should be able to duplicate the precise scientific process that you are working with in a step-by-step approach. It should be able to be configured to match your specific workflow process exactly. When I say exactly, I mean 100% without any changes to your actual scientific process. This is the standard that must be met, anything less should be rejected. A good Transgenic LIMS should also have the ability to be configured for changes in the workflow. This will allow for greater flexibility when scientific processes change or as a result of new scientific discoveries.

Conclusion

I think that if there were one important point that you should try to remember, then it would be to not underestimate your long-term automation needs. Not taking the time to fully understand how your research data moves through your organization could be a huge strategic mistake. Over the last five years Transgenic Software, Inc. has been researching and documenting this process and as a result, we have discovered that many companies are not prepared for the future. There will come a day when you will need to think of all of your research data in the context of a fully integrated research environment. This fully integrated environment will include all of the data related to your transgenic animal models. Ultimately this important data should be managed and controlled just like any of your other clinical study data. It is much better to be proactive on this front, than reactive.

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